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Tracheal fluid leakage in benchtop trials: comparison of static versus dynamic ventilation model with and without lubrication

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DOI: https://doi.org/10.1007/s00540-010-0871-z

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ZORA URL: https://doi.org/10.5167/uzh-40189
Journal Article
Published Version

Originally published at:
Dave, M H; Koepfer, N; Madjdpour, C; Frotzler, A; Weiss, M (2010). Tracheal fluid leakage in benchtop trials: comparison of static versus dynamic ventilation model with and without lubrication. Journal of Anesthesia, 24(2):247-252.
DOI: https://doi.org/10.1007/s00540-010-0871-z

J Anesth (2010) 24:247–252
DOI 10.1007/s00540-010-0871-z

ORIGINAL ARTICLE

Tracheal fluid leakage in benchtop trials: comparison of static versus dynamic ventilation model with and without lubrication

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Received: 20 August 2009 / Accepted: 12 November 2009 / Published online: 23 February 2010
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Abstract
Purpose Longitudinal folds in tracheal tube (TT) cuffs cause leakage of pooled secretions past the tube cuff, and the most common in vitro method to test the efficacy of a new tube is a benchtop model using an artificial rigid trachea. This study compared the potential of a static and dynamic ventilation benchtop model and cuff lubrication in testing the tracheal sealing properties of a given TT cuff.
Methods *Static trial* Six brands of 7.5 mm internal diameter (ID) cuffed TT ($n = 8$) with high volume–low pressure cuffs were inflated in an artificial trachea (18 mm ID) without and with lubrication. *Dynamic trial* The same tube cuffs, without lubrication, were subjected to positive pressure ventilation (PPV) + positive end-expiratory pressure (PEEP) of 5cmH$_2$O or to PPV alone (without PEEP) or to PEEP alone (without PPV). Clear water (5 ml) was placed above the tube cuff, and fluid leakage (ml) was measured up to 60 min.
Results Gel lubrication, PEEP alone and PPV + PEEP completely prevented fluid leakage across the tube cuffs in all six TT brands tested within 60 min when compared to the static unlubricated model (0% leak versus 100% leak; $P < 0.01$). Fluid leakage in the static unlubricated model and the PPV group was 1.38–4.76 ml and 0.23–4.47 ml, respectively.
Conclusion Gel lubrication, PEEP alone, and PPV + PEEP in the benchtop model had a much stronger protective effect than PPV alone on fluid leakage. Studies testing the fluid sealing efficiency of tube cuffs might be more conclusive in a static benchtop model without lubrication than in a dynamic model.

Keywords Tracheal tube cuff · PEEP · Benchtop trials · Aspiration

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Introduction

In the past decade, longitudinal folds in high volume–low pressure (HVLP) endotracheal tube cuffs have been recognized to cause leakage of pooled secretions past the tracheal tube (TT) cuff and to contribute considerably to ventilator-associated pneumonia in critically ill patients [1–4].

Numerous attempts have been made by researchers in the past to design a cuff that would provide an effective seal without leakage at lower transmitted cuff pressures. The most common and convenient in vitro method to test the efficacy of a new tube cuff in preventing fluid leakage is a benchtop model using an artificial rigid trachea. Investigators and reviewers are often keen to impose more stringent testing conditions, such as dynamic ventilation settings including positive end-expiratory pressure (PEEP) and/or adding lubrication on the cuff wall [5–10].

The aim of the present study was to test the effect of gel lubrication, positive pressure ventilation (PPV), and PEEP on fluid leakage in HVLP endotracheal tube cuffs.

Materials and methods

In an in vitro setup, fluid leakage past the TT cuff was evaluated using a polyvinylchloride (PVC) trachea of 18 mm internal diameter (ID), placed vertically upright. Six commercially available 7.5 mm ID endotracheal tube

Table 1 Investigated tracheal tubes with high volume–low pressure cuff

Tracheal tubes tested	Reference number	ID of tube (mm)	OD of tube (mm)	Cuff material	OD of cuff (mm)
Tapered seal guard tracheal tube (TSG) Covidien, Athlone, Ireland	109875	7.5	10.2	PU	20–27
Seal guard tracheal tube (SSG) Covidien, Athlone, Ireland	109675	7.5	10.2	PU	26
Microcuff tracheal tube Kimberly Clark, Zaventem, Belgium	35125	7.5	10	PU	22
Rueschelit super safety clear Rüsch GmbH, Kernen, Germany	112480	7.5	10	PVC	26
Portex profile soft seal SIMS Portex Ltd., Hythe, UK	100/199/075	7.5	10.3	PVC	30
Hi-Lo tracheal tube Covidien, Athlone, Ireland	109-75	7.5	10.2	PVC	30

PU polyurethane, *PVC* polyvinyl chloride, *ID* internal diameter, *OD* outer diameter

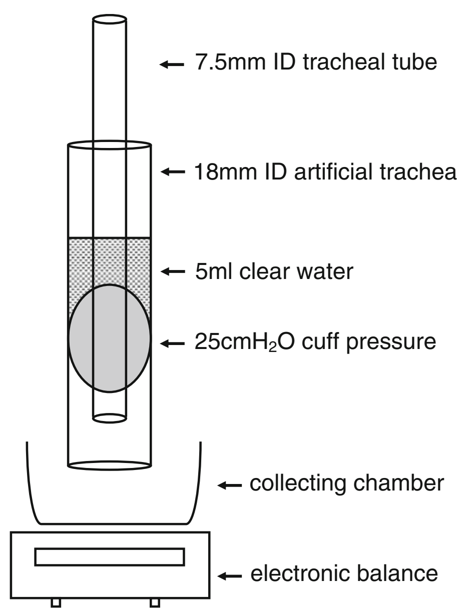

Fig. 1 Schematic representation of static artificial trachea model. *ID* internal diameter

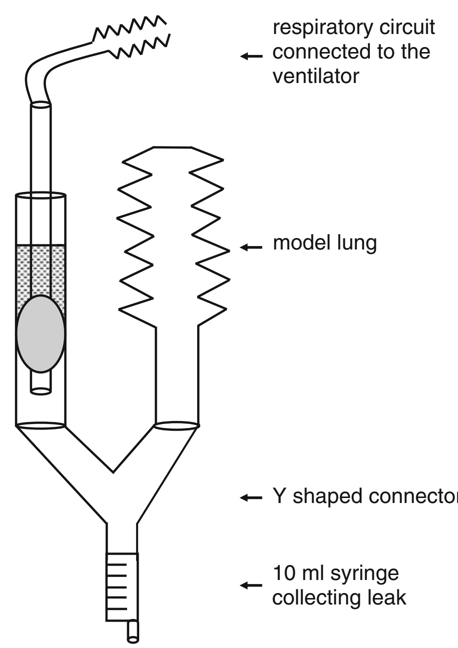

Fig. 2 Schematic representation of dynamic ventilation model

brands with HVLP tube cuffs were selected for testing (Table 1). The artificial trachea was intubated and the cuff inflated at 25 cmH_2O, which was continuously monitored by an automated digital cuff pressure manometer (VBM Cuff Controller; VBM Medizintechnik, Sulz, Germany). The tube was positioned with the lower cuff border 2.5 cm above the lower tracheal edge.

In the static setup (Fig. 1), tube cuffs were placed in the trachea without (static unlubricated group) and with (static lubricated group) gel lubrication (KY gel; Johnson and Johnson Medical, Arlington, VA, USA). Then, 5 ml clear water was applied above the tube cuff, and fluid leaking past the cuff was collected in a container below the model trachea. Fluid leakage was measured gravimetrically at 0, 0.5, 1, 2, 3, 4, 5, 10, 15, 30, and 60 min in this static setup. Because the specific gravity of pure water is 1.00, we could directly convert the measure leak in milligrams into milliliters.

In the dynamic trial (Fig. 2), the endotracheal tube cuffs were placed and inflated in the trachea without lubrication and attached to a test lung (Testlung; Carbamed, Zürich, Switzerland; compliance, 22 ml cmH_2O^{-1}). Respirator settings were fresh gas flow (air), 6 l min^{-1}; respiratory rate, 12 min^{-1}; peak inspiratory pressure, 20 cmH_2O; I:E ratio, 1:2. Dynamic trial was divided into different groups. In the PPV + PEEP group, positive pressure ventilation (PPV) was applied with 5cmH_2O PEEP. In the PPV group, PPV was applied without PEEP. In these groups, clear water (5 ml) was applied above the tube cuff, and fluid leakage was measured at the aforementioned time intervals up to 60 min, and in the PPV + PEEP group, also at 5 min after the release of PPV + PEEP. In the third group that is the PEEP group, endotracheal tube cuffs were placed in the artificial trachea as described above and attached to the respirator circuit but not ventilated; instead, a constant PEEP of 5 cmH_2O was applied, and fluid leakage noted for 60 min and again 5 min after the release of PEEP.

Experiments were repeated two times with four new tubes for each run in all six endotracheal tube brands (thus, eight observations per tube brand and group). Measurements were performed in randomized order at constant cuff pressures of 25 cmH_2O (continuously monitored). TT cuffs were inflated and checked by inspection before each test. Between experiments, the model was carefully cleaned and dried. Measurements were performed at room temperature, 22°–23°C.

Calculations and statistical analysis

The amount of fluid leakage at 60 min in the static unlubricated group was compared to that of all other groups tested using the Wilcoxon test. SPSS version 16.1 (SPSS, Chicago, IL, USA) from the hospital resources was used for this purpose. The statistical significance level was set at $\alpha = 0.05$. Fluid leakage at 5-min time intervals in the static unlubricated group was also compared to the data at 5 min after release of PPV + PEEP and PEEP using the Wilcoxon test. A similar nonparametric Wilcoxon test was also applied to compare the fluid leakage at 60 min in the PPV + PEEP and PPV groups.

Results

In the static model with unlubricated tube cuffs, maximum fluid leakage was observed in all PVC cuffs within the first 5 min (Fig. 3). In the polyurethane (PU) tube cuffs, water leakage was much less and was not complete even after 60 min (Fig. 3). Interestingly, gel lubrication in the static lubricated group prevented any water leakage during the first hour in all six tube brands (Table 2).

In the dynamic unlubricated setting using PPV + PEEP, no water leakage was detected in any of the six tube brands tested up to 60 min. During inspiration (positive pressure in the artificial lung), air bubbles moving from below the cuff upward along the longitudinal folds in the cuff wall were observed on a regular basis in all cuffs. Disconnection of the circuit and loss of positive pressure within the circuit after 60 min of PPV resulted in a leak within 30 s with all the six tubes tested. PPV without PEEP did not avoid water leakage, and the fluid leakage at 60 min corresponded to about 50% of that in the static unlubricated group in most of the tubes tested (Fig. 4).

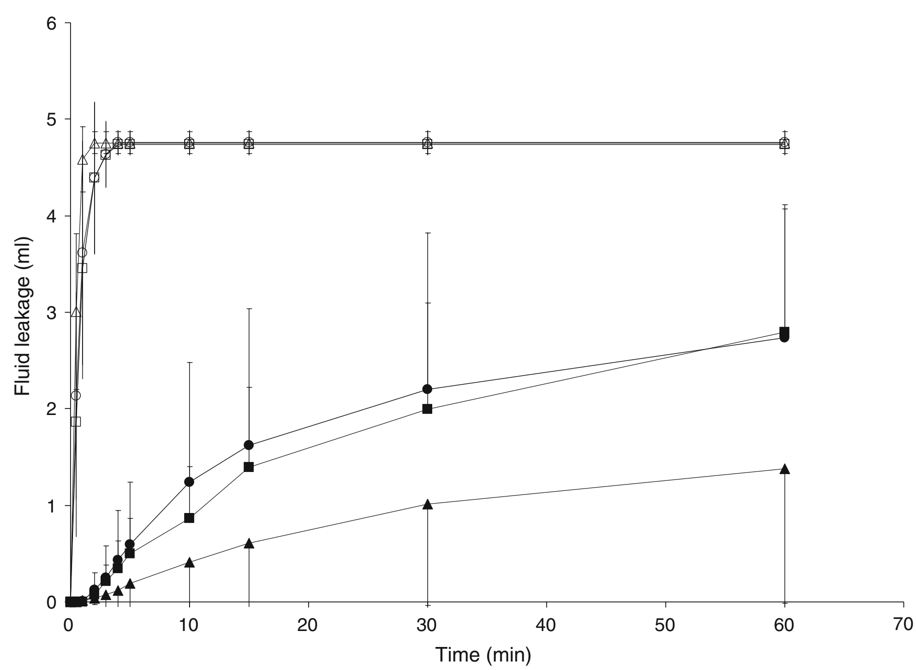

Fig. 3 Fluid leakage in the static unlubricated setup using 18 mm internal diameter artificial trachea (cuff pressure, 25 cmH_2O, 8 measurements per tube brand). Data are in mean (SD). *Filled circles* standard shape seal guard, *filled squares* tapered shape seal guard, *filled triangles* Microcuff, *open squares* Ruesch, *open triangles* Portex, *open circles* HiLo

Table 2 Fluid leakage past the tracheal tube cuff (ml)

Tracheal tube brand	Static		Static	Dynamic (PPV + PEEP group)		Dynamic (PPV group)	Dynamic (PEEP group)	
	Unlubricated		Lubricated	Unlubricated		Unlubricated	Unlubricated	
	5 min	60 min	60 min	After 60 min of PPV + PEEP	5 min after release of PPV + PEEP	After 60 min of PPV	After 60 min of PEEP	5 min after release of PEEP
Tapered seal guard (TSG)	0.50 (0.37)	2.79 (1.32)	0 (0)*	0 (0)*,#	0.29 (0.32)	0.23 (0.20)*	0 (0)*	0.34 (0.33)
Standard seal guard (SSG)	0.59 (0.64)	2.74 (1.33)	0 (0)*	0 (0)*,#	1.35 (0.98)	0.41 (0.14)*	0 (0)*	1.03 (0.97)
Microcuff	0.19 (0.29)	1.38 (1.39)	0 (0)*	0 (0)*,#	0.67 (0.54)	0.38 (0.17)	0 (0)*	0.76 (0.53)§
Rueschlit	4.74 (0.11)	4.74 (0.11)	0 (0)*	0 (0)*,#	4.73 (0.25)	2.15 (1.28)*	0 (0)*	4.77 (0.31)
Portex	4.76 (0.11)	4.76 (0.11)	0 (0)*	0 (0)*,#	4.71 (0.25)	2.56 (1.45)*	0 (0)*	4.55 (0.23)
Hi-Lo	4.76 (0.12)	4.76 (0.12)	0 (0)*	0 (0)*,#	4.61 (0.22)	4.47 (0.40)	0 (0)*	4.62 (0.26)

Data of 8 observations per tube are presented as mean (SD)

PPV positive pressure ventilation, *PEEP* positive end-expiratory pressure

* $P < 0.05$ for Wilcoxon test wherein 60-min leakage in static unlubricated group is compared to that of other four groups

# $P < 0.05$ for Wilcoxon test wherein 60-min leakage in PPV + PEEP group is compared to that of PPV group

§ $P < 0.05$ for Wilcoxon test wherein 5-min leakage in static unlubricated group is compared to 5-min leakage after release of PPV + PEEP and PEEP, respectively

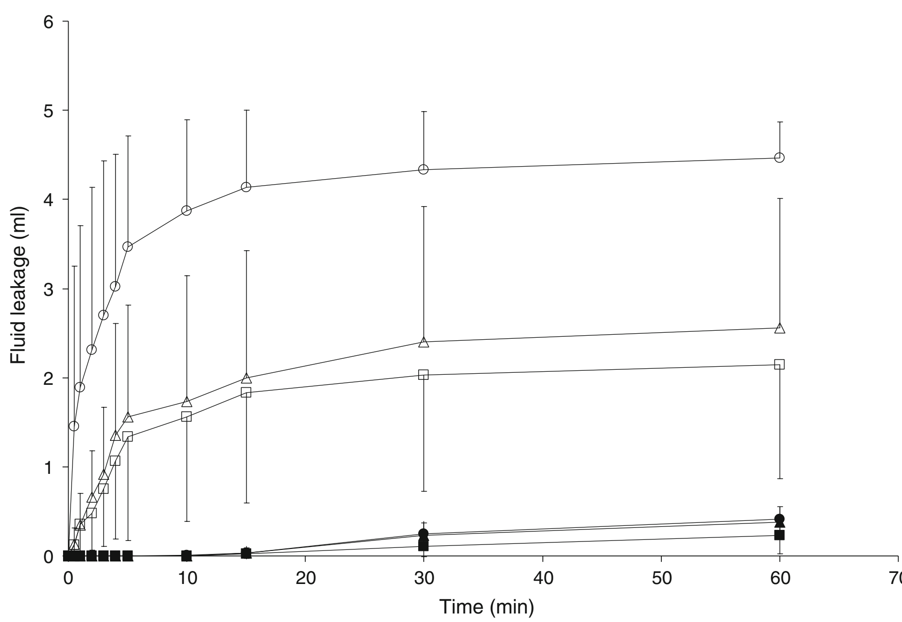

Fig. 4 Fluid leakage in the dynamic setup positive pressure ventilation (PPV) group [without positive end-expiratory pressure (PEEP)] in 18 mm internal diameter artificial trachea (cuff pressure, 25 cmH_2O; 8 measurements per tube brand). Data are in mean (SD). *Filled circles* standard shape seal guard, *filled squares* tapered shape seal guard, *filled triangles* Microcuff, *open squares* Ruesch, *open triangles* Portex, *open circles* HiLo

Finally, a constant PEEP of 5 cmH_2O alone prevented fluid leakage up to 60 min in all tube brands, and loss of this 5 cmH_2O PEEP resulted in a fluid leakage in a similar pattern as in the other static unlubricated trials. Data are summarized in Table 2.

Statistical analysis was performed between the 60-min leak in the static unlubricated group and all other groups using the Wilcoxon test (see Table 2). The difference was found to be statistically significant for all six tubes (*$P < 0.05$), with the only exception being that of Microcuff/Hilo in the PPV group. A similar nonparametric Wilcoxon test was also applied between the 60-min leak in the PPV + PEEP and PPV groups, and the difference was found to be statistically significant ($^{\#}P < 0.05$).

Fluid leakage at 5 min between the static unlubricated group and post release of PPV + PEEP and PEEP, respectively, was also compared using the Wilcoxon test; the difference was not found to be statistically significant, with the only exception being that of the Microcuff in the PEEP group ($^{\S}P < 0.05$).

Discussion

This trial investigated five different benchtop settings to test the tracheal sealing characteristics of HVLP tube cuffs. The main finding was that the static unlubricated model is the most stringent of all five models chosen to test the fluid sealing characteristics of a given TT cuff.

In vitro testing of TT cuff sealing characteristics is necessary to evaluate advances in cuff technology and thus to facilitate preselection of the better sealing tubes before their use in a clinical study. Tube cuff lubrication has been used by several investigators during in vitro trials to imitate a close contact of the cuff surface with the tracheal mucosa and filling of microchannels (longitudinal folds) with mucosal fluid. In these models, cuff lubrication reduced or prevented fluid leakage past the cuff, results similar to those of our study [11, 12]. The strength of the present study is the finding that cuff lubrication prevented fluid leakage even in those HVLP cuffs that have poor sealing characteristics.

Although earlier clinical studies [11, 12] have reported a protective effect of gel lubrication in cuffed tubes against fluid leakage, the effect is only transient and is lost after 24–120 h. Because there is no reliable protection against subglottic leakage in clinical practice, gel lubrication should be avoided when investigating sealing qualities in HVLP tube cuffs by in vitro models. The difference in the sealing characteristics of tube cuffs becomes more conclusive and evident under the static unlubricated setup, which could facilitate tube selection for in vivo trials in the future.

Positive pressure ventilation is used in benchtop trials to simulate real-life conditions (up-and-down movement of the tube within the trachea) and also to study the self-sealing effect of positive inspiratory pressure on ballooning of the tube cuff [13]. Our findings clearly demonstrate that sealing is much better in the PPV + PEEP setup as a consequence of the pneumatic effect generated by high pressure distal to the cuff tip. This pneumatic effect resulted in an air column filling the longitudinal folds, observed as bubbles moving up through the folds, and thus successfully prevented the leakage of fluid down the trachea. When positive pressure was lost in the circuit, the movement of the air bubbles stopped, emptying the longitudinal folds so they could be filled by the water droplets. This pneumatic protection seems to come more from PEEP rather than from PPV itself, as demonstrated in the PPV + PEEP group trial. This result is in agreement with the observations by Lucangelo et al. [13] wherein they showed that 5 cmH_2O PEEP has a protective effect on cuff leakage even in the absence of ventilation.

Disconnection of the breathing system from the trachea and a resulting pressure drop commonly occur during open and closed tracheal suction. The implications of the current findings are that in vitro studies investigating sealing characteristics of a new TT cuff should be done without lubrication and without PPV, because these conditions (PEEP, PPV, and gel lubrication) “conceal” the poor sealing characteristics of less-protective tube cuffs.

Limitations

This model of an intubated trachea, however, did not attempt to mimic the contact surface between the tracheal mucosa and the cuff wall, the static and the dynamic properties of the tracheal and extratracheal tissues during ventilation, the properties of different consistencies of secretions, or the effect of mucus on the cuff–tracheal interface. Fluids of different viscosities were not assessed, and it is possible that the rate of leakage would be reduced with more viscous secretions. All experiments were done in the vertical position in which gravity facilitates leakage across the cuff wall. In a supine, semirecumbent position, these data would need reevaluation.

Conclusion

We found that a static rigid trachea model, without lubrication, is more appropriate to test the tracheal sealing characteristics of a cuff rather than the ventilation model (PPV or PEEP). As low as 5 cmH_2O, PEEP alone has a protective effect on the cuff leak. Sudden loss of positive pressure in the system (disconnection) leads to rapid leak. Tubes that do not leak with gel or during ventilation may actually allow tracheal soiling with subglottic collections when used without the protective effects of lubrication and ventilation. The impact of the closed tracheal suction system on pressure drops and associated fluid leakage as a risk factor for ventilator-associated pneumonia needs further attention and investigation.

Acknowledgment This study was supported by departmental resources.

Conflict of interest statement The tracheal tubes tested were ordered from local distributors. Prof. Weiss was involved in the development and evaluation of new cuffed paediatric tracheal tubes in cooperation with Microcuff GmbH, Weinheim, Germany and Covidien, Athlone, Ireland.

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